Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Clinical development of Plant-made influenza VLP vaccines

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):**

**Authors/sponsors:** Nathalie Landry

**Study Design:** Phase II, Part A: 135 subjects randomized in a 2:2:2:2:1 ratio to receive 2 doses of the alum-adjuvanted H5 VLP vaccine, or non-adjuvanted H5 VLP or placebo

**Vaccine:** H5  
**Strain:**  
**Manufacturer:** Medicago

Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): recombinant, H5 VLP produced in N. Benthamiana plant  
**Adjuvant:** Al(OH)3  
**Delivery system/site:** IM injection  
**Doses (antigen and adjuvant):** 20 µg, 30 µg, 45 µg of HA protein per dose,  
Two doses at day 0 and 21

**Study population:** 135 adults  
**Age range:** 18-60  
**Health status:** Healthy volunteers  
**Specific inclusion criteria:**  
**Specific exclusion criteria:**

**Clinical Endpoints Assessed:**

**Safety assessments:** The following parameters were assessed: Local: pain, redness, swelling. Systemic reactions: muscle aches, headache, fatigue, feeling of general discomfort, joint aches, swelling in the axilla, swelling in the neck, chills.

**Immunogenicity assessments:**

- **Immunooassay type:**
  - HI
  - Neutralization (type of neutralization assay):
    - Others: SRH
  - Results:
  - **Safety:**
    The plant-made H5 VLP vaccine is well tolerated at all tested dose. Most AEs were mild and of short duration. No onset of allergic reactions after vaccination was demonstrated

**Immunogenicity:**

**GMTs**  
**GMT Ratios (post:pre)**  
Fold increase in HI after 2 doses:  
3.9  
6.1  
7.1  
**Per cent responding (4 fold or greater rise and definition for reporting):**  
HI ≥4 fold increase after 2 doses:  
37%  
57%  
65%  
**Per cent responders at specified titer:**  
HI ≥40 after 2 doses:  
37%  
57%
65% (20µg + Alum)

Others:

**Status of trial (ongoing/completed):** Completed